

**REMARKS**

This amendment is responsive to the Office Action of April 19, 2007. Reconsideration and allowance of claims 1-10, 12-15, and 22-26 are requested.

**Status of the Claims**

Claims 1-15 and 17-21 were pending as of the April 19, 2007 mailing date of the Office Action. Of these, claims 17-20 were withdrawn due to a previous telephonic election, and claims 1-15 and 21 were examined.

Claims 1-3, 5-8, 13, and 15 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Stephens, GB 1 426 319 (hereinafter "Stephens").

Claim 21 stands rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Kianl et al., U.S. Pat. No. 6,658,276 (hereinafter "Kianl").

Claims 4, 9, 10, and 14 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stephens in view of Kianl.

Claim 11 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stephens in view of Masuda et al., U.S. Pat. No. 6,322,516 (hereinafter "Masuda").

Claim 12 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Stephens in view of Tham et al., U.S. Pat. No. 5,912,656 (hereinafter "Tham").

Claims 11 and 12 also stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the enablement requirement.

The Office Action identifies the Stephens reference as a U.S. Pat. No. 1,426,319 which is a clearly unrelated patent not listing an inventor Stephens. Examiner Saidi identified the cited reference as GB 1 426 319 in a telephonic communication on July 12, 2007. Applicants ask that GB 1 426 319 be officially made of record in a Notice of References Cited in the forthcoming Office Action.

**Election of Group I is confirmed**

The telephonic election of Group I is confirmed. To expedite prosecution, claims 16-20 are canceled herein. Applicants reserve the right to prosecute these or similar claims in a continuation, divisional, or continuation-in-part application.

**The objections to the specification are addressed**

The specification is amended to remove reference to the claims. The amendments on page 2 substitute the text of claims 1, 21, and 16-20 for the claim citations. It is respectfully submitted that these amendments add no new matter, and as they obviate the objections to the specification they should be entered.

**The claims are amended for clarity and to address the drawing objection**

In claim 12, the objected "spider diagram" term is removed by amendment. Claim 11 which referenced a "tachometer display" is canceled. Claim 1 is amended for clarity. Claim 15 is amended to remove the "acoustic and/or optical" modifier, which is believed to obviate the drawing objection.

accordingly, it is respectfully requested that the objections to the claims and drawings, and the rejections under § 112, be withdrawn.

**The Stephens reference**

Stephens discloses a perfusion monitor that includes a perfusion index meter (12) that is initially adjusted as a basis for reference to read midscale such that subsequent readings show quantitatively any relative variation in perfusion expressed as a percentage. Stephens at page 4 lines 3-10. The perfusion index meter has a calibrated scale, such as a scale reading from 0% to 200% with a central reading of 100% corresponding to the reference. Stephens at page 1 lines 65-74.

The approach of Stephens overcomes some difficulties of the plethysmography curve conventionally used to present perfusion data, in that it extracts a quantitative perfusion index value and displays changes in this value compared with a reference perfusion index value. However, the approach of Stephens has a substantial deficiency in that the perfusion index meter does not provide information as to the selected reference perfusion index value. The clinician initially adjusts the perfusion index reader (12) to read at the midpoint (around 100%) for the current perfusion index value. It is not clear that the clinician has any knowledge of the reference perfusion index value. Even if the clinician somehow estimates the reference perfusion index value, for example based on how much adjustment is

required to set the perfusion index meter to 100%, this information is not conveyed by the perfusion index meter.

As a result, while the perfusion index meter (12) of Stephens provides information as to how much the perfusion index has changed since it was initially set up, it does not provide any information as to whether the change in perfusion index value is beneficial or detrimental. Thus, for example, if the reference perfusion index value was too low to start with, then a positive variation (i.e., increase) in the perfusion index value is indicative of patient progress. Using the perfusion index meter of Stephens, however, the clinician could misinterpret such a rise in the reading of the perfusion index meter (12) as a negative physiological indication.

A clinician may be called upon to work with a number of different patients using the Stephens device. The 100% level will typically represent a different perfusion index value for each patient. This can lead to confusion and, possibly, to medical errors.

#### **The Claims Distinguish Patentably Over the References of Record**

Claim 1 calls for a method for the presentation of information concerning variations of the arterial filling with blood of organs of living beings on a display unit, the method comprising: determining perfusion index data for presentation using an algorithm from measured values produced by a non-invasive photometric measuring process for determining the arterial oxygen saturation of the blood; defining a first perfusion index as a reference value; determining subsequent perfusion indices as relative deviations with respect to the reference value; displaying the reference value on the display unit; and presenting said relative deviations as information concerning the variations of the perfusion on the display unit.

Stephens presents relative deviations of perfusion index values from a reference value using the perfusion index meter (12), for example as percentage changes from the reference value. However, Stephens does not present the reference value itself. Stephens initially centers the perfusion index meter (12) such that the reference value always corresponds to 100%. Accordingly, there is no information as to the reference perfusion index value. This, in turn, can lead to misinterpretation of the relative deviations of perfusion index values displayed by Stephens.

In contrast, claim 1 calls for presenting said relative deviations and the reference value. In this way, the clinician is assured of having complete information to make medical decisions.

Claim 8 calls for first and second analog graphic elements to be used for the presentation of the reference value and the relative deviations, respectively. This arrangement ensures that the complete information including the reference value and the deviations is readily grasped by a clinician viewing the display unit.

Claim 9 further limits claim 8 by calling for first and second parallel bar elements to be used as the graphic elements, the first parallel bar element representing the reference value and the second parallel bar element representing the relative deviations. As noted in the specification at page 3 line 30 ff., this arrangement has been found by the inventors to be advantageous, because it ensures in a simple manner a fast visual and intuitive cognition by clinical staff.

Claim 10 further limits claim 8 by calling for the relative variations of the perfusion to be represented by a bar element, and the reference value to be represented by positioning of a reference graphic element respective to the bar element. The amendments to this claim are supported in the original specification at least by Fig. 5 and related text, where the bar (50) corresponds to the bar element and the arrow (54) corresponds to the reference graphic element. Again, this arrangement ensures in a simple manner a fast visual and intuitive cognition by clinical staff.

Claim 22 calls for a device comprising a pulsoximeter for determining arterial O<sub>2</sub> saturation and for providing perfusion data, and a display unit configured to display: a first graphical element indicative of a reference perfusion index value derived from the provided perfusion data at a reference time; and a second graphical element indicative of a subsequent perfusion index value derived from the provided perfusion data at a subsequent time. The display unit displays the first and second graphical elements together to provide a visual indication of a relative deviation of the subsequent perfusion index value from the reference perfusion index value.

At most, Stephens discloses the second graphical element indicative of a subsequent perfusion index value derived from the provided perfusion data at a subsequent time. This subsequent perfusion index value is shown by Stephens as a percentage deviation respective to a reference value centered at 100%.

Claim 23 calls for the first and second graphical elements to be parallel bar elements. Stephens does not disclose such an arrangement. Kianl is cited in the Office Action as showing the bar (610) in Fig. 6. However, this is a single bar, and hence cannot provide a graphical comparison between the current perfusion index value and the reference perfusion index value.

Claim 24 calls for the second graphical element to be a bar element, and for the first graphical element to be a graphical position indicator positioned at a point along the bar element to indicate the relative deviation of the subsequent perfusion index value from the reference perfusion index value. Claim 25 further limits claim 24 by restricting the graphical position indicator to be selected from a group consisting of an arrow and a line. Claims 24 and 25 read upon the embodiment illustrated in Fig. 5 of the present application.

Claim 26 calls for the display unit to be further configured to display arterial O<sub>2</sub> saturation determined by the pulsoximeter. This claim is supported, for example, by the numerical SpO<sub>2</sub> display (20) of the original specification.

In view of the foregoing, it is respectfully submitted that claims 1-10, 12-15, and 22-26 are in condition for allowance. Accordingly, Applicants respectfully request allowance of claims 1-10, 12-15, and 22-26.

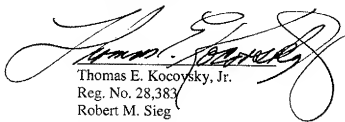
**CONCLUSION**

For the reasons set forth above, it is submitted that claims 1-10, 12-15, and 22-26 distinguish patentably over the references of record and meet all statutory requirements. An early allowance of all claims is requested.

In the event personal contact is deemed advantageous to the disposition of this case, the Examiner is requested to telephone the undersigned at (216) 861-5582.

Respectfully submitted,

FAY SHARPE LLP

A large, stylized handwritten signature in black ink, which appears to read "Thomas E. Kocovsky, Jr.", is written over the printed name and registration information.

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